EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

DWIGHT BRIGGS AND KONNIE BRIGGS,

Plaintiffs,

vs.

ENDOLOGIX INC., ENDOLOGIX LLC, and DEERFIELD MANAGEMENT COMPANY, L.P.,

Defendants.

Case No. _____

INDEX OF STATE COURT DOCUMENTS PURSUANT TO 28 U.S.C. § 1446(a) AND L.R. 81

Pursuant to 28 U.S.C. § 1446(a) and L.R. 81, Defendant Endologix Inc. hereby identifies each document filed and/or served in the state court action:

Tab	Description
Document A	State Court Docket
Document B	Complaint

DOCUMENT A

REGISTER OF ACTIONS
CASE NO. 119092-CV

Dwight Briggs and Konnie Briggs vs. Endologix Inc., a Delaware Corporation, Endologix LLC, a Delaware Corporation, and Deerfield Management Company, L.P., a Delaware Corporation

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Case Type: **Injury or Damage - Other Product Liability**
Date Filed: **08/10/2022**
Location: **149th District Court**

PARTY INFORMATION

		Attorneys
Defendant	**Deerfield Management Company, L.P.**	
Defendant	**Endologix, Inc.**	
Defendant	**Endologix, LLC**	
Plaintiff	**Briggs, Dwight**	**Charles R. Houssiere, III** *Retained* 713-626-3700(W)
Plaintiff	**Briggs, Konnie**	**Charles R. Houssiere, III** *Retained* 713-626-3700(W)

EVENTS & ORDERS OF THE COURT

	OTHER EVENTS AND HEARINGS
08/10/2022	**Original Petition (1-10 Plaintiffs) (OCA)**
08/10/2022	**Docket Sheet**
08/10/2022	**Jury Demand**

DOCUMENT B

Filed for Record
8/10/2022 6:11 PM
Donna Starkey, District Clerk
Brazoria County, Texas
119092-CV
Cathy Richard, Deputy

119092-CV

CAUSE NO. _____

DWIGHT BRIGGS and KONNIE BRIGGS	§	**IN THE DISTRICT COURT OF**
Plaintiffs,	§	
v.	§	**BRAZORIA COUNTY, TEXAS**
ENDOLOGIX INC., a Delaware Corporation, ENDOLOGIX LLC, a Delaware Corporation, and DEERFIELD MANAGEMENT COMPANY, L.P., a Delaware Corporation	§	
Defendants.	§	**_____ JUDICIAL DISTRICT**

PLAINTIFFS' ORIGINAL PETITION

TO THE HONORABLE JUDGE OF SAID COURT:

COMES NOW Dwight Briggs and Konnie Briggs, (collectively "Plaintiffs"), and file this Original Petition against Endologix, Inc., Endologix LLC (hereinafter "Endologix"), and Deerfield Management Company, L.P., (collectively "Defendants"), and for cause of action would respectfully show unto the Court the following:

I.

DISCOVERY CONTROL LEVEL

1. Plaintiffs intend that discovery be conducted under Discovery Level III pursuant to *Texas Rules of Civil Procedure 190.4*, and will seek an order, agreed or otherwise, to this effect.

II.

PARTIES

1. Dwight Briggs is an individual who at all times relevant to this cause of action was a resident of Pearland, Brazoria County, Texas.

2. Konnie Briggs is an individual who at all times relevant to this cause of action was a resident of Pearland, Brazoria County, Texas. Plaintiff Konnie is the spouse of Plaintiff Dwight.

3. Defendant Endologix, at all times relevant to this cause of action, was a Delaware corporation with principal executive offices at 2 Musick, Irvine, California 92618. Defendant Endologix develops, manufactures, markets, and sells medical devices primarily for the treatment of aortic disorders. Defendant Endologix is a resident and citizen of Delaware and California. Defendant Endologix may be served with process by serving its registered agent for service of process, Cynthia Pinto, at 2 Musick, Irvine, California 92618; or wherever she may be found.

4. Defendant Deerfield Management Company, L.P., at all times relevant to this cause of action, was a Delaware Limited Partnership with principal executive offices at. Defendant Deerfield Management Company is a healthcare investment firm. Defendant Deerfield Management Company, L.P. is a resident and citizen of Delaware and New York. Defendant Deerfield Management Company, L.P. may be served with process by serving its registered agent for service of process, The Corporation Trust Company, at Corporation Trust Center 1209 Orange St, Wilmington, DE, 19801.

III.

JURISDICTION AND VENUE

1. The Court has jurisdiction over this case because Endologix maintained sufficient minimum contacts with the State of Texas that the exercise of jurisdiction over Endologix would not offend traditional notions of fair play and substantial justice (general jurisdiction) and because this cause of action arose in the State of Texas (specific jurisdiction), and because the subject matter and monetary amount sought are within the Court's jurisdiction pursuant to applicable Texas law.

2. Venue is proper in Brazoria County, Texas, pursuant to Tex. Civ. Prac. & Rem. Code § 15.002(a)(1) in that all or a substantial part of the events and/or omissions giving rise to Plaintiffs' claims occurred in Brazoria County, Texas.

V.

FACTUAL BACKGROUND

1. An aneurysm occurs when an artery wall weakens, which allows the artery to abnormally balloon or widen.

2. An aortic arterial aneurysm ("AAA") is a serious medical condition because a rupture of the aortic artery can cause fatal internal bleeding.

3. Due to the risk of an AAA rupture, individuals such as Dwight Briggs may require surgery to repair, treat, and/or reinforce the artery wall.

4. Implantable aneurysm repair grafts are a type of medical device that have been developed to protect against ruptured aneurysms. At the most basic level, these repair grafts often function similar to a hose inserted into a damaged artery, which

permits blood to flow through the "hose" thereby avoiding the damaged portion of the artery.

5. Endovascular repair is a well-known surgical technique for AAA repairs. A surgeon implants an aneurysm repair graft device by inserting the device through an artery in the patient's leg and threading it up into the aorta/aneurysm.

6. Endoleaks occur when blood continues to remain or flow into the aneurysm cavity after the endovascular repair.

7. There are four types of endoleaks, ranging from type I-IV. Type I endoleaks occur when there is a gap between the repair graft and the vessel wall that allows blood to flow into the aneurysm cavity. Type II endoleaks occur when blood from a collateral vein flow into the aneurysm cavity. These are the most common type of endoleak and are typically considered to be benign. Type III endoleaks are attributed to device failures and occur when there is either a separation between the graft components (Type IIIa) or when there is a tear or hole in the graft material (Type IIIb). Type III endoleaks can result in aneurysm expansion and rupture. For this reason, Type III endoleaks require urgent or emergency medical attention. Type IV endoleaks occur when blood flows through the pores of the graft material and often resolve without intervention.

8. On October 26, 2015, Trivascular Technologies, Inc. agreed to merge with Endologix, Inc. Thus, Endologix, Inc. became the parent company of Trivascular Technologies, Inc.

9. On or about December 20, 2019, Dwight Briggs underwent an AAA repair surgery

and received a Trivascular, branded Ovation iX stent graft. This device was manufactured, marketed and sold by the parent company Endologix. The surgery was performed by Zvonimir Krajcer, M.D., at Baylor St. Luke's Medical Center ("BSL") located at 1101 Bates Ave, Houston, TX 77030.

10. Dwight Briggs subsequent monitoring and checkups continued at BSL and Texas Heart Medical Group. Dwight Briggs was presented with differing diagnoses between December 21, 2019, and August 13, 2020. For example, on January 19, 2017, Benjamin Cheong, M.D., concluded that Dwight Briggs had a "small type II endoleak." However, on a subsequent visit with Zvonimir Krajcer, M.D., on October 2, 2017, Dwight Briggs was informed that he had no endoleak at all. These conflicting diagnoses were constant and causing Dwight and Konnie Briggs to be concerned about the status of the device.

11. Seeking clarity, Dwight Briggs went to seek a second opinion with Charadutta Bavare, M.D., at Houston Methodist Hospital. Dr. Bavare diagnosed Dwight Briggs with a type III endoleak.

12. Dwight and Konnie Briggs were unaware that the originally implanted Ovation iX device had a defect or hole in the device until October 1, 2020. Dr. Bavare stated that the cause of the type III endoleak was because of a hole in the original stent produced by Endologix.

13. Dwight Briggs underwent multiple procedures to attempt to repair the type III endoleak. As of April 2022, the latest CT angiogram test appear to show that the endoleak is temporarily repaired. However, Dwight Briggs must undergo CT

angiogram tests every 6 months to ensure that the type III leak does not return.

14. As a direct and proximate result of the failed and defective Endologix device, Dwight Briggs had to undergo two stent repair procedures in addition to over thirty-six office visits and additional testing as of October 6, 2021.

15. As a direct and proximate result of the failed and defective Endologix Ovation iX device, Dwight Briggs has suffered significant harm, conscious pain and suffering, physical injury, bodily impairment, and disfigurement.

16. As a direct and proximate result of the failed and defective Endologix device, Dwight Briggs has suffered significant mental anguish and emotional distress and will continue to suffer physical limitations, pain, injury, damages, harm, and mental and emotional distress in the future.

17. As a direct and proximate result of the failed and defective Endologix device, Dwight Briggs has also incurred medical expenses and other economic harm, and will continue to incur such expenses and other economic harm in the future.

18. As direct and proximate result of the failed and defective Endologix device, Konnie Briggs has suffered a loss of consortium because of the loss of intimacy, affections, emotional support, marital relations, household chores, and other household services.

THE ENDOLOGIX OVATION iX ENDOVASCULAR AAA SYSTEM

19. On or about April 11, 2012, Defendant submitted a premarket approval application (PMA) to the United States Food and Drug Administrations (FDA) under Section 515 of the Federal Food, Drug, and Cosmetic act for a device it branded the Ovation

Abdominal Stent Graft System. See 21 U.S.C. § 360e et seq.

20. On or about October 5, 2012, Endologix received marketing approval from the FDA (subject to Defendant's adherence to additional Conditions of Approval) for its Ovation Abdominal Stent Graft System under Section 515 of the Act.

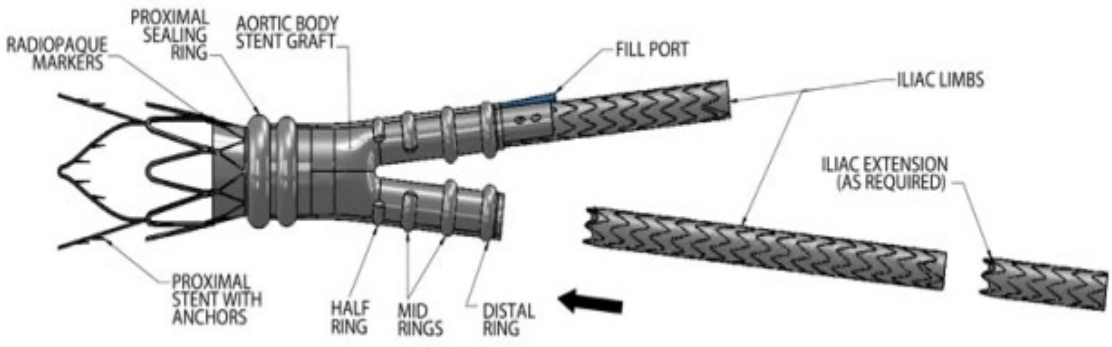
21. Pursuant to the approval process, Defendant was responsible for complying with the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); recalls (21 CFR Part 806), good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820), and the Conditions of Approval imposed in the devices approval letter.

22. In order to expand its product line and "expand the pool of patients eligible for [endovascular aortic repair]" Endologix developed a new AAA repair product called the Ovation iX Abdominal Stent Graft System. See, Trivascular Technologies 10Q for the Third Quarter of 2015.

23. Although Endologix considered the Ovation iX Abdominal Stent Graft System to be a new product, it did not submit a separate PMA application for the Ovation iX system. Instead, on or about May 4, 2015, Defendant submitted a real-time process PMA Supplement (Supplement-20) to enact a "Change Design/Components/Specifications/Material" for the Ovation Abdominal Stent Graft System.

24. Supplement-20 was approved on July 17, 2015 and shortly thereafter Endologix began marketing the device as the Ovation iX Abdominal Stent Graft System.

25. The Ovation iX Abdominal Stent Graft System modular configuration (as illustrated below) is comprised of an aortic body stent graft, iliac limbs, and iliac extensions. The remaining system includes a fill kit and autoinjector.



26. The device was intended to treat AAAs by providing a new path for the blood to flow so it does not fill and expand the aneurysm.

27. On August 6, 2018, Endologix issued a safety update regarding polymer leaks with the Ovation iX aortic body stent graft. In the safety update, Endologix reported that the increased rate of polymer leaks was due to incorrect implantation of the device.

28. On May 6, 2020, Endologix issued a recall letter notifying physicians that it was not the incorrect implantation of the Ovation iX device that was the root cause of the increased polymer leaks, rather it was a "material weakness" in the way the device was manufactured.

29. In the May 6, 2020, recall letter, Endologix made clear that the "letter provides information only; no product return is required" and that they "continue to work collaboratively with the FDA regarding updates to [the Ovatiaion iX] labeling." At that same time, Endologix was trying to convert as many physicians to using the new Alto model of stent graft. In fact, Endologix's CEO John Onopchenko refuted

the assertion that Endologix wanted to continue selling the Ovation iX system on the May 11, 2020 first quarter conference call to investors when he stated that "it is [Endologix's] intention to transition customers to Alto in geographies where Alto is approved" and that "[Endologix is] targeting 40 high and mid-volume Ovation iX sites."

30. On June 11, 2020, the FDA identified the recall as a Class I recall, finding that the use of the device may cause serious adverse health consequences or death.

PARALLEL FEDERAL REQUIREMENTS

31. Pursuant to federal law, a medical device is deemed to be adulterated if, among other things, it fails to meet established performance standards, or if the methods, facilities or controls used for its manufacture, packing, storage or installation are not in conformity with federal requirements. See 21 U.S.C. § 351.

32. Pursuant to federal law, a device is deemed to be misbranded if, among other things, its labeling is false or misleading in any particular, or if it is dangerous to health when used in the manner prescribed, recommended or suggested in the labeling thereof. See 21 U.S.C. § 352.

33. Pursuant to federal law, the FDA imposed several other additional requirements upon Endologix as Conditions of Approval of the Ovation iX Abdominal Stent Graft System. The FDA specifically stated in its approval letter for the device that "failure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA. The introduction or delivery for introduction into interstate commerce of a device that is not in compliance with its conditions of

approval is a violation of law." The FDA's letter further provided that the Center for Devices and Radiological Health of the FDA "does not evaluate information related to contract liability warranties . . . however, that device labeling must be truthful and not misleading."

34. Pursuant to federal law, the Ovation system's Conditions of Approval require Endologix to submit a PMA Supplement when unanticipated adverse effects, increases in the incidence of anticipated adverse events, or device failures necessitate a labeling, manufacturing, or device modification. In accordance with federal law, a medical device manufacturer may submit a PMA Supplement to change a device's warning without prior FDA approval. 21 CFR § 814.39(d)(2).

35. Upon information and belief, after receiving information concerning the increased incidence of Type III endoleaks with the Ovation iX device, Endologix failed to submit a PMA supplement to adequately apprise the Plaintiff and his doctors of the increased risk of Type III endoleaks in violation of its legal obligations.

36. Pursuant to federal law, the Ovation system's Conditions of Approval required Endologix to create and provide a clinical update to physicians at least annually. In addition to other information, this update was specifically required to provide physicians relevant information from Endologix's commercial experience (adverse event reporting). Upon information and belief, Endologix failed to adequately comply with these federal requirements and instead attempted through numerous methods to conceal in its annual clinical update to physicians the increased risk of Type III endoleaks with the Ovation iX device.

37. Endologix was aware of the increased incidence of endoleaks prior to Mr. Briggs receiving Defendant's defective product on December 20, 2019. If Endologix had timely submitted a PMA supplement, or timely provided an annual update prior to Mr. Briggs receiving Endologix's defective product on December 20, 2019, Mr. Briggs and his doctors would have been apprised of the increased risk of endoleaks and would not have used Endologix's defective product on December 20, 2019, but would have used an alternative non-defective product.

COUNT I.
STRICT LIABILITY IN TORT

1. Plaintiffs incorporate by reference all statements and allegations contained above.
2. Defendant Endologix designed, assembled, manufactured, constructed, inspected, installed, used, distributed, sold, or otherwise introduced into the stream of commerce the Ovation iX device and its component parts which were unreasonably dangerous to users and consumers, and which did not contain or include adequate safety warnings.
3. The Ovation iX device at issue and its various component parts were in a defective and unreasonably dangerous condition at the time they left the hands of Defendant Endologix in that it deviated from product specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death. Further, the Ovation iX device at issue and/or its component parts reached the expected consumer and/or user without substantial change in that condition.
4. The Ovation iX device at issue and its component parts were in a defective and unreasonably dangerous condition at the time of the first sale, lease, use or consumption. Due to defective conditions and parts, the Ovation iX device was not in

accordance with industry standards and Endologix failed to comply with the FDA's MDR regulations. See 21 U.S. Code § 360i and 21 C.F.R. § 803.50(a).

5. The device was manufactured in a manner violative of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 321 et seq. and applicable FDA regulations. The facilities or controls used by Defendant in the manufacture, packing, storage, or installation of the devices were not in conformity with applicable regulations and FDA-approved specifications for the device or the CGMP requirements set forth in FDA's quality system regulations, 21 C.F.R. Part 820.
6. The Ovation iX device was unreasonably dangerous because
    a. The utility of the stent to the user and to the public as a whole was outweighed by the gravity and likelihood of injury from its use. The likelihood the stent would fail to repair the AAA, causing the patient to risk serious injury or death outweighed any utility of the stent to the Plaintiff or to the public as a whole.
    b. A substitute product which would meet the same need and not be unsafe or unreasonably expensive was available. Stents manufactured with lower incidences of fabric tearing or holes in the graft material were available. See FDA Circulatory System Devices Panel published report on November 2, 2021 finding that "Endologix had the highest proportion of reports for Type III Endoleaks" of any other manufacturer on the market from January 1, 2016 to July 31, 2021.
    c. Defendants had the ability to eliminate the unsafe character of the stent without seriously impairing its usefulness or significantly increasing its costs. For

example, manufactures with significantly lower rates of endoleaks used better graft materials, methods of material manufacturing, graft thickness, and delivery system.

d. Neither Plaintiff not his surgeon was aware (and it could not be anticipated they would be aware) of the danger the stent would have a hole or defect in the materials, causing the patient to develop a type III endoleak; or, of how to prevent or avoid that danger. These dangers in the stent were not general public knowledge or obvious.

e. Neither Plaintiff nor his surgeon expected the graft to have a hole or defect in the material causing a type III endoleak; and expected the material to not have a hole in it or a defect in the material.

7. The above five factors considered holistically, with no single factor needing to be proven on its own, working together show that the stent was unreasonably dangerous.

8. Dwight Briggs is a person who was reasonably expected to use or be affected by the use of the Ovation iX device and its component parts. The Ovation iX device, however, was defectively designed.

9. As a direct and proximate result of Plaintiff's use of Defendant's Ovation iX device, as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. Defendant Endologix is strictly liable for any injuries resulting from the described defective and unreasonably

dangerous products without consideration of fault.

10. Defendant is strictly liable for selling and distributing medical devices in an unsafe, defective, unreasonably dangerous, and/or improperly manufactured condition in violation of Texas law and parallel federal requirements.

COUNT II.
NEGLIGENT DESIGN, MANUFACTURE, PRODUCTION, PREPARATION, INSTALLATION, ASSEMBLY, TESTING AND/OR INSPECTION OF THE SUBJECT DEVICE

1. Plaintiffs incorporate by reference all statements and allegations contained above.
2. Defendant Endologix owed a duty to Plaintiffs to design, manufacture, produce, prepare, install, assemble, test, and inspect the described Ovation iX device and its component parts in a reasonably safe manner.
3. Defendant Endologix breached this duty by designing, manufacturing, producing, preparing, installing, assembling, testing, and/or inspecting the Ovation iX device and/or its component parts in a negligent and unreasonable manner in that when it left the hands of the Defendant, the foreseeable risks of the product exceeded the benefits associated with its design or formulation, or it was more dangerous than an ordinary consumer would expect, and/or it failed to comply with federal requirements for these medical devices.
4. Due to negligence, the Ovation iX device failed to adequately protect Plaintiffs in this foreseeable event. The foreseeable risks associated with the design or formulation of the Endologix Ovation iX device, include, but are not limited to, the fact that the design or formulation of the Endologix Ovation iX device is more dangerous than a reasonably prudent consumer would expect when used in an intended or reasonably foreseeable

manner, and/or it failed to comply with federal requirements.

5. Multiple other products with safer alternative designs exist that are approved to treat AAA with comparable or better efficacy.
6. FDA's initial approval of the Endologix Ovation system device does not insulate Defendant from liability for injury or harm caused by use of the product due to design defect, because FDA has determined that the device is dangerous to health and safety when used as directed and required a Class I recall.
7. The allowance of damages under Texas law for harm caused by a defectively designed medical device that remained on the market due to a manufacturer's failure to comply with federal requirements, provides a parallel remedy for a violation of federal standards and does not conflict with the oversight of medical devices by the federal government.
8. As a direct and proximate result of Plaintiff's use of the Endologix Ovation system, as manufactured, designed, sold, supplied, marketed and introduced into the stream of commerce by Defendant and/or its failure to comply with federal requirements, Plaintiffs have sustained serious injuries and damages in an amount in excess of the jurisdictional minimum of this court.

COUNT III.
NEGLIGENT FAILURE TO WARN/BREACH OF DUTY TO WARN PLAINTIFF OF DEFECTIVE CONDITION OF SUBJECT DEVICE

1. Plaintiffs incorporate by reference all statements and allegations contained above.
2. Defendant Endologix is the manufacturer, designer, distributor, seller, and/or supplier of aortic treatment devices, including the Endologix Ovation iX device for use in AAA

repair.

3. The Endologix Ovation iX device manufactured, designed, marketed, distributed and sold by Defendant was defective due to inadequate warning or instruction because at the time it left the control of Defendant and was supplied to Plaintiff, Defendant knew or should have known that its product was unreasonably dangerous, as confirmed by its own internal data, because the Ovation iX device substantially and significantly increases the risk of Type III endoleaks compared to other treatment options for AAA repair. Despite this knowledge, Defendant failed to adequately warn Plaintiff and/or his physicians of the increased risk or provide adequate instructions for the devices safe use.
4. Defendants made the following representations regarding its Ovation iX graft:
    a. Its unique helical nitinol stent is engineered to be kink resistant even in the most tortuous anatomies
    b. A 0% rate of type I and Type III endoleaks at 4 years.
5. Defendants merely gave the following warning regarding the Ovation iX graft:
    a. The long-term performance of this implant has not been established. All patients treated with this device must undergo periodic imaging to evaluate stent graft integrity and position, aneurysm size, and potential endoleaks and/or, occlusion of vessels in the treatment area.
6. The product contained one or more marketing defects:
    a. There was an inherent risk in the entended or reasonably foreeable use of the product that the product could have a hole or defect in the stent graft materials,

causing a type III endoleak.

b. There was inadequate warning in that, among other things:

i. The warnings were not placed in a location to reasonably be expected to catch the attention of the user (the surgeon), such as on the product packaging itself;

ii. The warnings failed to inform the user (the surgeon) of the nature of the danger, such as that the graft material could have a hole or material defect in it and cause the patient to develop a type III endoleak;

c. Defendant knew or reasonably foresaw (or should have known or reasonably foreseen) the above risks (that the graft material could have a hole or defect in it, causing the patient to develop a type III endoleak).

d. Defendant failed to warn the surgeon (or to adequately warn the surgeon) that the graft material could have a hole or defect in it, causing the patient to develop a type III endoleak, failed to instruct the surgeon (or failed to adequately instruct the surgeon) how to safely use the product, or both.

7. If Defendants had informed Plaintiff's surgeon that the graft material could have a hole or material defect in it and cause a type III endoleak, Plaintiff's surgeon would have used Defendant's Ovation iX graft to repair Plaintiff's AAA. Because Plaintiff's surgeon used Defendant's Ovation iX graft, the mesh had a hole or defect in it, causing Plaintiff to develop a type III endoleak. The type III endoleak resulted in Plaintiff undergoing two repair surgeries and over thirty-six other visits to treat the condition. If Plaintiff's surgeon had chose a different graft (as he would have if had had been

informed of the above risks), Plaintiff's graft would have properly treated his AAA and Plaintiff would not have needed the two graft repair surgeries and the additional thirty-six follow ups.

8. Multiple other products with safer alternative designs exist that are approved to treat AAA with comparable or better efficacy.

9. FDA's initial approval of the Endologix Ovation iX device does not insulate Defendant from liability for injury or harm caused by use of the product due to failure to adequately warn or instruct, because FDA has determined that the device is dangerous to health and safety when used as directed and required a Class I recall.

10. The allowance of damages under Texas law for harm caused by a medical device that failed to provide adequate warning or instruction, in that FDA has determined the Endologix Ovation iX device is a hazard to human health and subject to a Class 1 recall, and therefore Texas law provides a parallel remedy for a violation of a federal standard and does not conflict with the oversight of medical devices by the federal government.

11. The allowance of damages under Texas law for harm caused by the Endologix Ovation iX device that failed to provide adequate warnings and instructions for use, and that remained on the market due to a manufacturer's failure to comply with federal requirements, provides a parallel remedy for a violation of federal standards and does not conflict with the oversight of medical devices by the federal government.

12. As a direct and proximate result of Plaintiff's use of the Endologix Ovation iX device as manufactured, designed, marketed, distributed, and sold by Defendant and/or its failure to comply with applicable federal requirements, Plaintiff suffered serious

physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

COUNT IV. NEGLIGENCE

1. Plaintiffs incorporate by reference all statements and allegations contained above.
2. Defendant had a duty to exercise reasonable care in the design, manufacture, sale and/or distribution of the Endologix Ovation iX device into the stream of commerce, including a duty to assure that its product did not pose a significantly increased risk of bodily harm and adverse events and/or a duty to comply with federal and state requirements.
3. Defendant failed to exercise ordinary care in the design, formulation, manufacture, sale, testing, quality assurance, quality control, labeling, marketing, promotions and distribution of the Endologix Ovation iX device into interstate commerce in that Defendant knew or should have known that the product caused significant bodily harm and was not safe for use by consumers, and/or through failure to comply with federal and state requirements.
4. Despite the fact that Defendant knew or should have known that the Ovation iX device, posed a serious risk of bodily harm to consumers, Defendant continued to manufacture and market the Ovation iX device for use by consumers and/or continued to fail to comply with federal and state requirements.
5. Defendant knew or should have known that consumers such as the Plaintiff would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as described above, including the failure to comply with federal and state requirements.

6. FDA's initial approval of the Endologix Ovation iX device does not insulate Defendant from liability for injury or harm caused by use of the product due to design defect or failure to warn or instruct, because FDA has determined that the device is dangerous to health and safety when used as directed and required a Class I recall.
7. The allowance of damages under Texas law for harm caused by a defectively designed medical device and/or a medical device that fails to provide adequate warning or instruction that FDA has determined is a hazard to human health and subject to a Class I recall provides a parallel remedy for a violation of a federal standard and does not conflict with the oversight of medical devices by the federal government.
8. The allowance of damages under Texas law for harm caused by a defectively designed medical device and/or a device that failed to provide adequate warnings and instructions for use that remained on the market due to manufacturer's failure to comply with federal requirements, provides a parallel remedy for a violation of federal standards and does not conflict with the oversight of medical devices by the federal government.
9. As a direct and proximate result of Defendant's negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
10. Defendant is liable for negligently selling and distributing medical devices in an unsafe, defective, unreasonably dangerous, and/or improper condition in violation of Texas law and parallel federal requirements.

COUNT V. NEGLIGENCE PER SE

1. Plaintiffs incorporate by reference all statements and allegations contained above.
2. Defendant has an obligation not to violate the law in the manufacture, design, testing, assembly, inspection, labeling, packaging, supplying, marketing, selling, distribution, advertising, preparing for use, warning of the risks and dangers of the Ovation iX device.
3. Defendant's acts described above constitute an adulteration, misbranding, or both, as defined by the Federal Code 21 U.S.C. § 351, 21 U.S.C. § 352, and other applicable FDA regulations, and constitute a breach of duty subjecting Defendant to civil liability for all damages arising therefrom under the theory of negligence per se.
4. Plaintiff, as a purchaser of the Defendant's device, are within the class of persons the statutes and regulations described above are designed to protect, and Plaintiff's injuries are the type of harm these statutes and regulations are designed to prevent.
5. As a direct and proximate result of Defendant's breach of the federal statutory requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.
6. Defendant is liable for negligently selling and distributing medical devices in an unsafe, defective, unreasonably dangerous, and/or improper condition in violation of Texas law and parallel federal requirements.

COUNT VI. FRAUD

1. Plaintiffs incorporate by reference all statements and allegations contained above.
2. Defendant has a duty not to deceive consumers and their physicians, including Plaintiff's, about the Ovation iX device.

3. Prior to Plaintiff's implantation surgery in December 20, 2019, Defendants made representations (and/or omissions) to Plaintiff and/or his physicians regarding the character and/or quality of the Ovation iX device for guidance in their decision to select the Ovation iX device for Plaintiff's use.
4. Defendant failed to disclose in its labeling, advertisements, and/or promotions that the Ovation iX device had an increased risk of type III endoleak failures, particularly as compared to other AAA repair devices.
5. Defendant represented to Plaintiff and/or Plaintiff's physicians that its device was safe and met all applicable design and manufacturing requirements.
6. Defendant stated in its July 2015 IFU for physicians that no Type III endoleaks were identified through 12 months post-treatment of the Ovation iX Abdominal Stent Graft Clinical Study. However, Endlogix admitted that this finding was solely from the study of the Ovation abdominal stent graft and that "based on the similarities of the Ovation iX Abdominal Stent Graft System to the Ovation Abdominal Stent Graft System and the nonclinical testing, the clinical data obtained on the Ovation Abdominal Stent Graft System from the clinical study is applicable to the Ovation iX Abdominal Stent Graft System as well."
7. Defendant represented to Plaintiff and/or Plaintiff's physicians in its marketing materials and website that the endoleaks that Endologix did identify was "likely due, in part, to high-quality imaging" and was a result of the device itself.
8. The Endologix Ovation iX system, manufactured and sold by Defendant, did not conform to these representations.

9. Plaintiff to his detriment reasonably relied upon Defendant's misrepresentations and omissions in its labeling, advertisements, and promotions concerning the serious risks posed by these products. Plaintiff reasonably relied upon Defendant's representations to Plaintiff and/or Plaintiff's health care providers that the Endologix Ovation iX device was safe for use.
10. Plaintiff reasonably relied to his detriment upon Defendant's misrepresentations and omissions in its labeling, advertisements, and promotions concerning the benefits of these products. Plaintiff reasonably relied upon Defendant's representations to Plaintiff and/or Plaintiff's health care providers that the Endologix Ovation iX system possessed beneficial characteristics such as providing safe treatment for abdominal aortic aneurysms when in reality it did not.
11. FDA's initial approval of the Endologix Ovation iX device does not insulate Defendant from liability because FDA has determined that the device is dangerous to health and safety when used as directed and required a Class I recall.
12. The allowance of damages under Texas law for harm caused by fraud provides a parallel remedy for violation of federal standards.
13. The allowance of damages under Texas law for harm caused by fraud does not conflict with the oversight of medical devices by the federal government, particularly when FDA has determined the device is a hazard to human health and subject to a Class I recall.

14. As a direct and proximate result of Defendant's fraud, Plaintiff was implanted with Defendant's Ovation iX device and Plaintiff suffered serious physical injury, harm,

damages and economic loss and will continue to suffer such harm, damages and future economic loss.

DAMAGES

1. As a direct and proximate result of Defendants' negligence, Plaintiffs suffered severe personal injuries, pain, suffering, mental anguish, disability, impairment, disfigurement, lost wages, lost earning capacity and have incurred reasonable and necessary medical expenses for the care and relief of their injuries. For a long time to come, if not for the rest of their lives, Plaintiffs will continue to suffer physical injuries, physical impairment, disfigurement, pain and suffering, disability, and mental anguish. Additionally, as a result of the incident, Plaintiffs will incur reasonable and necessary medical expenses in the future.

2. Plaintiffs seek exemplary damages as allowed by law in an amount to be determined at trial. When viewed objectively, Defendants' conduct, acts and/or omissions described above involved an extreme degree of risk, considering the probability and magnitude of potential harm to others. Defendants had actual, subjective awareness of the risk but proceeded with a conscious indifference to the rights, safety, or welfare of others. Defendant's conduct rises to the level of gross negligence. Accordingly, Plaintiffs are entitled to a finding that Defendants were grossly negligent concerning the incident.

3. Plaintiffs also seek punitive damages from the Defendants under Tex. Civ. Prac. & Rem. Code Ann. Section 41.003 for their gross negligence/malice that resulted in Plaintiffs' injuries and damages as set forth herein above. Plaintiffs prefer to leave the precise amount of damages to the sole determination of the jury, based upon the credible evidence presented at trial, without regard to sympathy, prejudice, or bias. In accessing punitive damages against Defendant,

the jury should take into account the following considerations: 1) the nature of the Defendant's wrong; 2) the character of the conduct involved; 3) the degree of culpability of the wrongdoer; 4) the situation and sensibilities of the parties concerned; 5) the extent to which such conduct offends a public sense of justice and propriety; and 6) Plaintiffs' reasonable attorney's fees. *Alamo National Bank v. Kraus*, 616 S.W.2d 908, 910 (Tex. 1981). The jury should also be guided by previous exemplary sums, if any, paid by or on behalf of the Defendant for the same or similar unsafe practices alleged in this case. The jury should also take into account the net worth of the Defendant.

4. Plaintiffs now sue for all of these damages in an amount that exceeds the minimum jurisdictional limit of this Court. Pursuant to Texas Rule of Civil Procedure 47, Plaintiffs assert that they are seeking monetary relief in excess of monetary relief over $1,000,000.

5. Plaintiffs are entitled to recover prejudgment and post judgment interest as allowed by law.

XVII.

CONDITIONS PRECEDENT

1. All conditions precedent have been performed or have occurred to support Plaintiffs' pleadings and causes of action.

XVIII.

JURY DEMAND

1. Plaintiffs demand a jury trial and tender the appropriate fee with this petition.

PRAYER

1. Plaintiffs pray that Defendant be cited to appear and answer this petition and that on final trial, Plaintiffs have judgment against Defendant for:

a. All medical expenses in the past and future;

b. Mental anguish in the past and future;

c. Physical pain in the past and future;

d. Physical impairment in the past and future;

e. Lost wages and loss of earning capacity in the past and future;

f. Disfigurement in the past and future;

g. Prejudgment and post judgment interest as allowed by law;

h. Exemplary Damages;

i. Costs of suit; and

j. Such other and further relief to which Plaintiffs may be justly entitled.

Respectfully submitted,

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Tomeca Fenner on behalf of Charles Houssiere, III
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Status as of 8/11/2022 7:23 AM CST

Case Contacts

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